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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,829	10/20/2004	Motoo Sumida	47233-0045 (219711)	8556
55694 7590 12/28/2009 DRINKER BIDDLE & REATH (DC) 1500 K STREET, N.W. SUITE 1100 WASHINGTON, DC 20005-1209				
EXAMINER				
CUTLIFF, YATE KAI RENE				
ART UNIT		PAPER NUMBER		
1621				
MAIL DATE		DELIVERY MODE		
12/28/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/511,829

**Applicant(s)**

SUMIDA ET AL.

**Examiner**

YATE' K. CUTLIFF

**Art Unit**

1621

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5, 8 - 21 & 24, 27 - 35 is/are pending in the application.
- 4a) Of the above claim(s) 8 - 14, 19, 20 & 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 15 - 8, 21, 24, 27 & 29 - 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 4, 5, 8-21, 24 and 27-35 are pending.  
Claims 2, 3, 6, 7, 22, 23, 25 and 26 have been canceled  
Claims 8 – 14, 19, 20 and 28 have been withdrawn.  
Claims 1, 4, 5, 15 – 18, 21, 24, 27 and 29 - 35 are rejected.

### ***Response to Arguments***

2. Applicant's arguments, see page 6, filed October 28, 2009, with respect to the objection of claims 15 - 19 have been fully considered and are persuasive in view of the arguments, the fact that the claims were renumbered during prosecution and MPEP 608.01(n)(IV). The objection of claims 15 - 19 has been withdrawn.
3. Applicant's arguments filed October 28, 2009, with regard to the 35 USC 103(a) rejection of claims 1, 4, 5, 15 – 18, 21, 24, 27 and 29 - 35 have been fully considered but they are not persuasive, for the reasons set out in the Office Action Mailed September 2, 2009 and as set out below.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4, 5, 15 – 18, 21, 24, 27 and 29 - 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Kuniaki, et al. (JP 01-202261, English translation), Yukihiisa et al. (JP 11-290094, English translation) and Kleinig (Univ. Heidelberg, 1967, abstract); for the reasons set out in the Office Action mailed September 2, 2009 and as set out below.

8. Applicant respectfully asserts that although *Yukihiisa* does mention astaxanthin fatty acid monoesters generally (See, e.g., p. 8, para. 8 of the English translation), the object of *Yukihiisa* is to form diesters. Also, stating that *Yukihiisa's* examples show

formation of a mixture of free astaxanthin, monoester, and diester, in which the yield of the diester is optimized. *See, e.g., Examples 1-9 of the English Translation.* Asserting that *Yukihisa* fails to explicitly disclose using monoesters in food or cosmetic compositions. Furthermore, asserting that based on these facts, one of ordinary skill in the art at the time of Applicant's invention would have expected from the teachings of *Kuniaki, Kleinig, and Yukihisa* that it is preferred to form astaxanthin fatty acid diesters. Thus, there is no suggestion or expectation from the references that one of ordinary skill in the art would produce astaxanthin medium-chain fatty acid monoesters.

9. In response, Examiner states that the *Yukihisa et al.* reference discloses a process for preparing fatty acid monoesters of astaxanthin in an esterification reaction with fatty acids having 14 to 22 carbon atoms and lipase. (see [0001]. Also, in the reaction process of *Yukihisa et al.*, between a fatty acid and free astaxanthin, it is suggested that when the ratio of fatty acid to free astaxanthin is less than 2 times mole, a high content of fatty acid diesters cannot be attained. (see [0013]). Furthermore, even though the monoester produced, was contained in a mixture of free astaxanthin and astaxanthin fatty acid diester, it was produced. Additionally, according to the teaching of *Yukihisa et al.* the fatty acid monoester produced by their reaction can be removed from the product mixture by HPLC. (see Example 10). It is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. (In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747,

750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792,794, 215 USPQ 569,570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983)).

10. Applicant respectfully asserts that when discussing fatty acids, persons of ordinary skill in the art typically group the fatty acids into long-chain, medium-chain, and short-chain. That these groups are delineated at least because each group is expected to have differing properties. Further, that the Office has provided no evidence to support the conclusion that astaxanthin esterified with fatty acids from each of the different groupings would perform similarly. Additionally, Applicant asserts that their fatty acid monoester of astaxanthin has greater digestibility. .

11. In response, Applicant's claim 1 is to a purified medium chain fatty acid ester of astaxanthin. Applicant has provided no information on the levels of purity so to ascertain a difference between their claimed product and one that can be easily produced by any of the processes disclosed in the references; Kuniaki, et al., Yukihiisa et al. and Kleinig; and where the monoester can be then separated from any mixture of fatty acid esters of astaxanthin by HPLC. The Examiner has presented references that disclose processes for esterification of astaxanthin with fatty acids of chain length that essentially bracket the claimed compounds. Additionally, according to Yukihiisa fatty acid monoesters have absorption efficiency in the enteric canal that is superior to free astaxanthin. (see Yukihiisa [0005] page 6). The enteric canal is apart of the human digestive system, where absorption of food takes place. For these reasons, as those previously set out (Sept. 2, 2009), the Examiner states that the claims are obvious. An

obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties. Where prior art compounds essentially bracket the claimed compounds and are well known pesticides, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new pesticides. (In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979).

Further, any evidence that the claimed purified medium chain fatty acid ester of astaxanthin provide greater digestibility than a monoester fatty acid produced by any one of the process taught by the references has not been provided, i.e. the process of Yukihiisa et al. Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. Dillon, 919 F.2d at 692-93, 16 USPQ2d at 1901. A showing of unexpected results must be based on evidence, not argument or speculation. In re Mayne, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) (conclusory statements that claimed compound possesses unusually low immune response or unexpected biological activity that is unsupported by comparative data held insufficient to overcome prima facie case of obviousness).

12. Finally, Applicant respectfully asserts even if, *arguendo*, the structures of the esters described in *Kuniaki*, *Yukihiisa*, and/or *Kleinig* were similar enough to establish a *prima facie* case of obviousness, the unexpected and superior results discovered by the

Applicant of using astaxanthin C8 to C10 fatty acid monoesters rebut such a finding.

13. In response, the Examiner states, the references relied on by the Examiner disclose process for producing such esters, as such show that the public would be put in possession of astaxanthin medium-chain fatty acid esters where the medium-chain fatty acid has 8 to 10 carbon atoms. Further, based on the teaching of Yukihiisa et al. it was known in the art at the time of Applicant's claimed invention that fatty acid monoesters of astaxanthin were useful in foods and pharmaceutical agents; and had greater absorption efficiency in parts of the human digestive system than free astaxanthin.

Rebuttal evidence may include a showing that the prior art fails to disclose or render obvious a method for making the compound, which would preclude a conclusion of obviousness of the compound. A conclusion of obviousness requires that the reference(s) relied upon be enabling in that it put the public in possession of the claimed invention. The court in *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968), stated: Thus, upon careful reconsideration it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. [footnote omitted.] In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. The



Hoeksema court further noted that once a *prima facie* case of obviousness is made by the PTO through citation of references, the burden is on the applicant to produce contrary evidence establishing that the reference being relied on would not enable a skilled artisan to produce the different compounds claimed. *Id.* at 274-75, 158 USPQ at 601. See also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 295, 297, 227 USPQ 657, 666, 667 (Fed. Cir. 1985) (citing Hoeksema for the proposition above).

Therefore, for the reasons set out above, and in the Office Action mailed September 2, 2009, the invention as a whole was *prima facie* obvious because a person of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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